REMARKS

Claims 32-42 are pending in this application. No further amendments to the claims are made herein. Claims 1-31 and 43-46 were canceled previously without prejudice and without disclaimer of the subject matter contained therein. Accordingly, claims 32-42 are before the Examiner.

August 10, 2006 Information Disclosure Statement

Applicants note that an initialed Form SB08a has not been mailed indicating that the August 10, 2006 IDS has been considered by the Examiner. The IDS, citation sheets, and reference copies are all available through PAIR and Applicants received a copy of the date stamped returned postcard indicating receipt by the PTO on August 10, 2006. Applicants respectfully assert that the IDS was filed nearly two months prior to the mailing of the current office action. Applicants respectfully request consideration of the August 10, 2006 IDS and that a copy of the initialed Form SB08a be mailed to Applicants. To the extent that a new rejection is issued based on any of the references contained in the IDS, applicants respectfully request that it be made non-final.

Power Of Attorney and Correspondence Address

A Power of Attorney with Revocation and related documents were filed on August 8, 2003 and accepted by the Office on September 18, 2003 indicating the Power of Attorney and Correspondence Address be associated with customer no. 35139. It appears that the Office changed the Power and Correspondence address to customer no. 25291 in January 2005 in response to an EBC Customer Number Update. However, there is no record of any change in Power of Attorney or revocation since August 2003. Accordingly, the Power of Attorney to the practitioners of customer number 35139 is still in effect. Applicants submit herewith a Request

for a Change of Correspondence Address changing the address to that of customer no. 35139. Applicants respectfully request that the Office make the appropriate changes prior to the next mailing and that all future correspondence be directed to customer no. 35139.

Obviousness Type Double Patenting

Claims 32-42 remain rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,479,535. As noted previously, Applicants respectfully request that the rejection be held in abeyance until an indication of allowable claims, upon which time Applicants may file a terminal disclaimer.

Claim Rejections 35 U.S.C. § 103

The Action, maintains the previous 103 rejections over combinations of Raveendranath or Miller, each with Gibson. In the Response to Arguments section, on page 12, the Action states:

> It would have been obvious from the teachings of Gibson et al. to employ the specific amounts of wetting agents, glidants, etc. in the composition taught by Raveendranath et al., and Miller et al. because 2-(4-Hydroxy-phenyl)-3-methyl-1-[4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol, which has two phenolic hydroxyl groups, and significantly similar structure (indole and benzothiophene are closely related heterocyclic aromatic compounds), and similar substituents as raloxifene, would be expected to have similar solubility in water as raloxifene.

Applicants note, however, that the cited compound and raloxifene do in fact differ in some significant ways. First, the "similar substituents" referred to appear to be the (2-piperidin-1-yl-ethoxy) portion of the structures. Notably, these side chains are on different portions of the heterocycle. In raloxifene, the side chain is attached to a carbon atom at the 3 position of the heterocycle. In sharp contrast, in Applicants' compound, the side chain is attached directly to the heteroatom, nitrogen, while a methyl group is at the 3 position. This alone would lead one of ordinary skill in the art to believe the two would have different solubilities.

The expected differences in solubility coupled with the fact that Gibson et al., on its face, is limited to "certain benzothiophenes" including raloxifene would lead one skilled in the art *away*

from combining Gibson et al. as suggested. It is only Applicants' specification that teaches Applicants' formulations may be used for both raloxifene and the compounds of the present claims (Applicants' claims have been amended to claim combinations employing only indols and not raloxifene or other benzothiophenes). Gibson et al. does not teach or suggest that the formulation disclosed for "certain benzothiophenes" would be applicable to indols or any other type of compound.

Additionally, the side chain in raloxifene contains a ketone, which is not present anywhere in Applicants' claimed compounds. Thus, those of skill in the art would not reasonably expect the formulation of Gibson et al. to be effective with the compounds found in Raveendranath et al. and Miller et al. or Applicants' claims. Accordingly, the rejection based on obviousness should be withdrawn.

Only Applicants' specification teaches raloxifene and Applicants' claimed indols would benefit from Applicants' formulation. There is nothing in the art that suggests such formulations would benefit both benzothiophenes and indols. The Office has relied upon impermissible hindsight when employing the references, using the Applicants' specification as a guide. There simply is no teaching or suggestion, absent Applicants' specification, that teaches or suggests that formulations enhancing the solubility of benzothiophenes would also be useful with indols.

Additonally, applicants note that to support a finding of obviousness with regard to optimization of ranges, the art must recognize the variable to be optimized is a result effective variable (see MPEP § 2144.05 II, and in re Antonie, 559 F.2d 618 (CCPA 1977)). Nothing in Gibson, Miller or Raveendranath teaches or suggests that any of the claimed

For all the reasons outlined above, and previously, Applicants respectfully assert that the obviousness rejection should be withdrawn.

With respect to claims 32-34, Applicants respectfully assert that the recited combinations do not teach or suggest the specific pharmaceutical composition of each of the claims. Claims

32-34 each claim specific filler/disintegrant, disintegrant, wetting agent, antioxidant, glidant, and lubricant components, as well as concentration ranges for each. These specific combinations are neither taught nor suggested by Gibson et al.

For example, Applicants' claim 32 requires lactose, microcrystalline cellulose, pregelatinized starch, ascorbic acid, sodium lauryl sulfate, sodium starch glycolate, silicon dioxide, and magnesium stearate, in various concentrations. None of the fifteen examples in Gibson et al. contains any of microcrystalline cellulose, pregelatinized starch, or ascorbic acid. The art is silent with respect to the use of microcrystalline cellulose, although cellulose derivatives such as hydroxypropyl methylcellulose and sodium carboxymethylcellulose are mentioned and appear in some examples. Gibson et al. teaches only that in raloxifene formulations, enhanced bioavailability is achieved by including a combination of a surfactant, a water-soluble diluent, and an optional hydrophilic binder.

The Commissioner is hereby authorized to charge any fee or underpayment thereof or credit any overpayment to deposit account no. 50-1275.

Early reconsideration and allowance of all pending claims is respectfully requested. The examiner is requested to contact the undersigned attorney if an interview, telephonic or personal, would facilitate allowance of the claims.

Respectfully submitted,
COZEN O'CONNOR

/Michael A. Patané/

Date: February 12, 2007

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